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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,712

02/02/2007

Eran Eilat

EILAT3

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 10/582,712	<b>Applicant(s)</b> EILAT, ERAN	
	<b>Examiner</b> Mina Haghighatian	<b>Art Unit</b> 1616	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 24 February 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): The rejection of claims under 35 USC 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraph.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 82-91.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 02/24/11  
 13. ☐ Other: \_\_\_\_\_.

/Mina Haghighatian/  
Primary Examiner, Art Unit 1616

Continuation of 11. does NOT place the application in condition for allowance because:

The amendments are entered, and they overcome the rejection of claims under 35 U.S.C 112. However the amendments, Remarks and the Declaration fail to place the claims in condition for allowance.

Firstly, Applicant argues against the finality of the last office action, because it contained a new reference and new rejection. In particular Applicant argues that since the Cortifoam reference has been applied for the first time, the finality of the office action is improper. Applicant also argues that the office action could not be made final because of removal of Tamarkin reference due to applicant predating the reference. The above arguments are not found persuasive. Tamarkin was removed because it was predated and not due to amendments. As such removal of Tamarkin as prior art did not result in the finality of the action. The amendments of 09/20/10, after the non-final action, cancelled all pending claims and introduced new claims, which contained different limitations. As a result they required a new search and examination. To meet the newly added limitation of a device including a container and a pipe, Cortifoam reference was introduced which discloses a device comprised of a container and a pipe. The remaining references relied upon (namely, Purwar et al, Abram et al and Klein et al) are the same references used in the Non-final office action.

Then Applicant argues that Cortifoam reference can not anticipate the claims because it is drawn to a foam for application of hydrocortisone acetate to anal region and not to the ear. It was disclosed in the office action that "for dispensing medication to the ear" is an intended use and is not support for patentability. Applicant does not disclose how the two products are different, but merely argues the difference in use. Both products are foams containing an active agent placed in a device that comprises a container and a pipe. Hydrocortisone acetate is a steroid. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

The submitted Declaration compares a foam formulation to a solution formulation and concludes that the foam formulation is more efficient. In this regard, Applicant states that "the Declaration proves that the foam-based formulation application method of the present invention is unexpectedly superior in efficacy as compared to the eardrops of Purwar". While this statement is not disputed, the arguments are not persuasive because the rejections were based on Purwar et al in view of Cortifoam or Abram et al. Cortifoam and Abram et al are drawn to a foam formulation. It is known by the persons of ordinary skill in the art that foam provides added contact time for the active agent and as such would be expected to have superior results compared to a solution. It would have been obvious to one of ordinary skill in the art to have prepared the formulations of Purwar et al for treating disorders of the ear in the form of a foam as taught by Cortifoam and Abram et al which would have resulted in a more efficient treatment.

It has been held that "[w]hen an application simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007) (quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent application claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is MORE than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742. Consistent with this reasoning, it would have been obvious to have selected a foam form for the formulations of Purwar et al for treating disorders of the ear as disclosed by prior art's disclosure, to arrive at a process "yielding no more than one would expect from such an arrangement".

Additionally, the burden of demonstrating unexpected results rests on the party asserting them. It has been long held that "even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art, unless the claimed ranges 'produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art.'" In re Huang, 100 F.3d 135, 139, 40 USPQ2d 1685, 1688 (Fed. Cir. 1996) (quoting In re Aller, 220 F.2d 454, 456, 105 USPQ 233,235 (1955), and citing In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed. Cir. 1990)).

All pending claims remain rejected for the reasons of record.